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7 **UNITED STATES DISTRICT COURT**
8 **DISTRICT OF NEVADA**
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10 BAYER SCHERING PHARMA AG, *et*
11 *al.*,

12 Plaintiffs,

13 v.

14 LUPIN LTD., *et al.*,

15 Defendants.

Case No. 2:10-CV-01166-KJD-RJJ

ORDER

16 Presently before the Court is Plaintiffs' Motion to Reset the Effective Date of the FDA's
17 approval for the Defendants to Market Generic YAZ® (#109). Defendants filed a response (#111) to
18 which Plaintiffs replied (#117).

19 **I. Facts and Procedural History**

20 Bayer has marketed its oral contraceptive YAZ® since March 2006. In 2010, Defendants
21 filed an ANDA to market a generic version of YAZ®. On July 15, 2010, Bayer filed suit against the
22 Lupin Defendants alleging that Lupin's ANDA constituted an act of infringement of the '564 patent
23 under 35 U.S.C. § 271(e)(2). Bayer sought damages, injunctive relief, and an order setting the
24 effective date of the FDA's approval of Watson's ANDA as no earlier than the expiration date of the
25 '564 patent. See Doc. 1, 11/5/2007 Watson Complaint at 6-9.
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1 Upon the filing of the lawsuit, a stay commenced under 21 U.S.C. § 355(c)(3)(C) preventing
 2 the FDA from approving Lupin's ANDA until the expiration of thirty months or the resolution of the
 3 litigation on the merits. If the litigation lasted longer than thirty months, the FDA could approve the
 4 ANDA, and the generic applicant could then market its generic product at the risk of incurring
 5 damages for infringing sales if this Court found the '564 patent valid, infringed, and enforceable.

6 On March 30, 2012, in Case No. 2:07-cv-01472-KJD-GWF, this Court granted Bayer's
 7 motion for summary judgment of non-obviousness, finding that the '564 patent was valid. See Case
 8 No. 2:07-cv-01472-KJD-GWF, Doc. 106, 3/30/2012 Order. The parties had already stipulated to the
 9 '564 patent's enforceability and Lupin's infringement. See Doc. 86, 7/22/11 Stipulation Regarding
 10 Infringement And Enforceability of U.S. Reissue Patent No. 37,564.

11 The Court also granted Bayer's motion for summary judgment of no non-obviousness. See
 12 Doc. 334, 3/30/2012 Order. Because the parties had already stipulated to Lupin's infringement of the
 13 '564 patent, the Clerk entered judgment in favor of Bayer and against Lupin. See Doc. 107,
 14 4/11/2012 Judgment in a Civil Case.

15 II. Analysis

16 Under Hatch-Waxman, upon a finding that an ANDA-filer has infringed a valid patent, the
 17 Court shall order that the effective date of the FDA's approval of the ANDA be no earlier than the
 18 expiration date of the patent-in-suit. 35 U.S.C. § 271(e)(4)(A). If the FDA has already approved the
 19 ANDA, the trial court resets the effective date of approval until after the expiration of the infringed
 20 patent. Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1366 (Fed. Cir. 2008).

21 Despite Defendants' disagreement with the underlying finding of infringement, the plain
 22 language of 35 U.S.C. § 271(e)(4)(A) provides that upon a showing of an ANDA-filer's infringement
 23 of a valid and enforceable patent:

24 the court ***shall order*** the effective date of any approval of the drug . . . product
 25 involved in the infringement to be a date which is not earlier than the date of the
 26 expiration of the patent which has been infringed.

35 U.S.C. § 271(e)(4)(A) (emphasis added).

1 Therefore, the Court orders that the effective date of the FDA's approval of Watson's and
2 Sandoz's YAZ® ANDAs be set no earlier than June 30, 2014.

3 III. Conclusion

4 Accordingly, IT IS HEREBY ORDERED that Plaintiffs' Motion to Reset the Effective Date
5 of the FDA's approval for the Defendants to Market Generic YAZ® (#109) is **GRANTED**;

6 IT IS FURTHER ORDERED that the effective date of the FDA's approval of Lupin's YAZ®
7 ANDA be set no earlier than June 30, 2014;

8 IT IS FURTHER ORDERED that Plaintiffs shall serve a copy of this order on the FDA.

9 DATED this 11th day of February 2013.

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13 Kent J. Dawson
14 United States District Judge
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